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February 6, 2020

By FedEx (to Research Triangle Park Addresses) and Email (to Mr. Witt)

Ethylene Oxide Commercial Sterilization
Section 114 Survey Response
U.S. Environmental Protection Agency
Office of Air Quality Planning and Standards
Sector Policies and Programs Division
Fuels and Incineration Group
Mail Code E143-05
109 T.W. Alexander Drive
Research Triangle Park, NC 27711
(Letter and DVD Containing Non-CBI Response and Non-CBI Attachments)

U.S. Environmental Protection Agency
Office of Air Quality Planning and Standards
U.S. EPA Mailroom (C404-02)
Attn: Ms. Tiffany Purifoy, Document Control Officer (ESD #322)
109 T.W. Alexander Drive
Research Triangle Park, NC 27711
(Letter and DVD Containing Full Response and All Attachments)

Mr. Jonathan Witt
U.S. Environmental Protection Agency
Office of Air and Radiation
witt.jon@epa.gov
(Letter Only)

Re: Sterigenics U.S., LLC's Response to December 9, 2019 Clean Air Act Section 114(a) Information Request for Commercial Sterilization NESHAP

Dear Mr. Witt et al.:

This letter, the enclosed Excel workbooks and attachments, and the attached Addendum constitute the Response of Sterigenics, U.S. LLC ("Sterigenics" or the "Company") to EPA's Clean Air Act ("CAA") Section 114(a) Information Request for the "Ethylene Oxide Commercial Sterilization Section 114 Survey" ("Request") dated December 9, 2019 addressed to Phil Macnabb and received by Sterigenics by email on December 10, 2019.[1] The Request set a response date of February 6, 2020.

Sterigenics supports EPA's rulemaking activity and is pleased to provide information to support that activity. To that end, Sterigenics previously hosted EPA staff at its Charlotte, North Carolina facility for a facility tour earlier in the rulemaking process. Sterigenics now responds to the Request with the enclosed workbooks and attachments for each of its nine U.S. facilities. This letter and its Addendum also comprise part of Sterigenics' response (the "Response").

[1] The address block for EPA's letter addresses the Request to Mr. Macnabb as president of Sterigenics and also, on the line below his title, to "Sotera Health." Sterigenics is the proper party for receipt of the Request because it owns and operates all of the facilities listed in EPA's cover letter. Sotera Health LLC is the parent company of Sterigenics.

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On January 13, 2020, Sterigenics requested an extension of time to respond to the Request, citing the voluminous nature of the information requested for each of nine Sterigenics facilities. On January 23, 2020, EPA denied the extension request and asked Sterigenics to submit this Response by the original February 6, 2020 due date. Sterigenics has made every reasonable effort to collect the requested information in the time available, with a focus on the information that we anticipate will be most pertinent to EPA's rulemaking. The Company has not been able to answer every request in this limited time period and has, therefore, left some spreadsheet cells blank for that reason.

In providing its Response, Sterigenics conducted a reasonable and diligent inquiry of personnel at the listed facilities and Sterigenics' corporate offices in Oak Brook, Illinois, and conducted a reasonable and good-faith effort to identify, locate, and collect responsive information. As a result of those efforts, Sterigenics collected the responsive, non-privileged information and documents provided in the Response.

Further clarifications of Sterigenics' response are provided in the Addendum attached to this letter. This letter, the Addendum, and the enclosed Excel workbooks and attached documents are all part of the Company's response.

Pursuant to 40 C.F.R. §2.203, Sterigenics hereby asserts a claim that the information and all documents attached to the workbooks with file names that end in "CBI" are confidential business information ("CBI"), and Sterigenics requests confidential treatment for them under 40 C.F.R. Part 2. CBI is marked according to EPA's instruction. Tabs within the "CBI" workbooks that contain CBI contain "Yes" in Cell N2, and cells containing CBI are highlighted in red. EPA may only release such CBI to its contractors pursuant to confidentiality agreements that are consistent with the requirements of 40 C.F.R. Part 2.

We are available to discuss or clarify any information in this Response at your request For any further questions, please feel free to contact me at khoffman@sterigenics.com or 630.928.1758.

Sincerely,

KAHoffman

Kathleen Hoffman
Senior Vice President - Global Environmental,
Health & Safety and Technical Services

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Addendum to Response of Sterigenics U.S., LLC
to EPA's Section 114 Request for Information Dated December 9, 2019

General Clarifications

1. As noted in the cover letter, the Request seeks a vast amount of information requested in a short time period. Sterigenics appreciates and supports EPA's desire to collect accurate data to represent the commercial sterilization industry as it engages in rulemaking, and the Company has sought to provide as much information as it can reasonably collect during the limited time period. Nonetheless, the Company has not been able to collect or develop all of the information requested. In most cases in which information is not available, Sterigenics has left spreadsheet cells blank.

2. Sterigenics is currently voluntarily adding additional air pollution control devices and control efficiencies to its facility in Charlotte, North Carolina. These additional controls are not required by federal, state, or local rules, but the Company nevertheless applied for and received a permit to construct and operate from Mecklenburg County, North Carolina. Construction began on January 27, 2020 and is estimated to be finished by late April 2020. Sterigenics has answered the Request based on the modified configuration of the Charlotte facility.

3. Sterigenics recently added additional air pollution control devices and control efficiencies to its facility in Atlanta, Georgia. These additional controls are not required by federal, state, or local rules, but the Company and Georgia EPD entered into an agreed order to allow construction to begin in advance of a permit from Georgia EPD. Construction is complete; however, the facility temporarily is not operating for unrelated reasons. Sterigenics has answered the Request based on the modified configuration of the Atlanta facility.

4. Sterigenics appreciates the need for accurate information and has taken reasonable care to ensure the accuracy of its Response; however, it has not endeavored to fill out the information requested in the "Certification" tab of the model Excel workbook. EPA's Request calls for a large amount of data from multiple facilities over a multiyear timeframe, making it difficult for any individual person to certify a response. Moreover, Sterigenics is not aware of any requirement in the Clean Air Act for a certification or the implied requirement to retain a professional engineer or certified industrial hygienist to provide or develop the requested information.

Clarifications to Particular Cells in the Excel Workbook

Request A-21: *Provide diagrams of your facility indicating all rooms, primary ethylene oxide emission points (e.g., regulated emission points), and secondary ethylene oxide emission points (e.g., fugitive emission points). Ensure that all natural draft openings are adequately labeled.*

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Response: Sterigenics has provided general site layout diagrams for this response and has not had time to develop new diagrams where necessary to include all of the requested information.

Request A-25: *Provide the startup, shutdown and malfunction (SSM) plan approved for your facility .*

Response: Sterigenics notes that the relevant NESHAP does not require commercial sterilizers to prepare startup, shutdown and malfunction ("SSM") plans. (*See* 40 C.F.R. § 63.360, Table 1.) Sterigenics has detailed company policies and standard operating procedures that govern all aspects of its operations, including responsible operation during startup, shutdown, and malfunctions. However, the Company does not interpret the Request to ask for this information, which would be voluminous.

Request A-28 to A-35: *Enter longitude and latitude of each building corner, specified to sixth decimal point.*

Response: Sterigenics has provided this information to the extent available. The Company notes that some interpretation of what constitutes a "corner" (e.g., in the case of a stack or other structure built above the general roof level) was required, and it has used reasonable judgment to make those interpretations.

Request A-37: *Provide materials sterilized at your facility with ethylene oxide.*

Response: Sterigenics has provided, for each facility, a general description of the most commonly sterilized products. Please note that product mix can change over time.

Request A-38: *Provide the approximate percentage of total materials sterilized with ethylene oxide based on volume of material throughput.*

Response: Many of Sterigenics' facilities sterilize 100 percent of their total materials with ethylene oxide. A few also sterilize with propylene oxide. For those latter facilities, Sterigenics has generally interpreted "volume" as referring to the percent of total pallets sterilized with ethylene oxide. If it was not possible in the time provided to obtain percent of total pallets sterilized with ethylene oxide, the Company left the spreadsheet cell blank.

Request A-39: *Provide the approximate percentage of total materials sterilized with ethylene oxide based on dollar amount.*

Response: Please see the clarification for Request A-38. The Company was not able to analyze revenue records for facilities that sterilize less than 100 percent of their pallets with ethylene oxide, so for those facilities, Sterigenics has left the field blank.

Request A-40 to A-41: *Provide annual ethylene oxide stack and fugitive emissions of the facility for the last five years.*

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Response: Sterigenics notes that mass emissions of ethylene oxide are necessarily estimates. Sterigenics has applied a consistent methodology across its facilities to estimate emissions for this response.

Request A-44: *Provide the average annual growth rate in revenues from ethylene oxide sterilization services for the last five years.*

Response: Sterigenics has not been able to collect and analyze this information in the time provided.

Request B-12 to B-21: *For each natural draft opening ("NDO") in each room, provide identification, type, latitude and longitude to sixth decimal point, cross-sectional area, height above ground, whether air is forced out of the NDO, and air velocity.*

Response: Sterigenics is able to provide this information for its Atlanta and Charlotte facilities, as it recently had an outside consultant survey those facilities as part of engineering for recent facility upgrades that include negative pressure enclosures throughout these facilities. Because a complete and reliable identification of natural draft openings requires a time-consuming survey of the facilities by a consultant trained in the requirements of EPA's Method 204, Sterigenics has not been able to provide the requested information for its other facilities in the time provided.

Request E-8 to E-20 and E-37 to E-39: *Provide, for each sterilization chamber, information on temperature, relative humidity, pressure, ethylene oxide dose, nitrogen and air washes, product dwell time, time that product spends in the chamber before being moved out, and ethylene oxide concentration achieved (reduced to) before the product is moved out of the chamber.*

Response: Sterigenics has provided data (which generally includes averages, maxima, and minima); however, Sterigenics notes that these parameters depend on the products being sterilized. The product mix can change over time; therefore, these data should not be considered representative of future operations.

Request G-28: *For each engineering or non-regulatory emission test performed in the last five years on any air pollution control device, specify the date and average dollar cost and provide a copy of the test.*

Response: As part of its response to Request G-17, Sterigenics has provided all performance (stack) tests performed in the last five years. Sterigenics has not attempted to provide any other tests, however, as it is unsure what scope of test, diagnostic information, or operating information EPA has in mind.

Request I-1 to I-8: *List all personal (badge) monitoring events for ethylene oxide during the last five years, including: unique identifier; date; description of work conditions of facility during each event; average, minimum, and maximum concentration; any action level, error, or flag of result; any average period; instruments used; and detection limit for those instruments.*

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Response: Sterigenics has provided minimum and maximum concentrations from its program of personal (badge) monitoring conducted quarterly on an eight-hour, time-weighted average basis to meet OSHA requirements. Sterigenics notes that these data are likely to be of limited use, as they: (1) do not represent concentrations in any particular area of the facility; (2) are not useful in estimating emissions, as they include concentrations in areas – such as aeration rooms – that are vented to existing air pollution control devices; and (3) do not represent inhalation exposure to employees, as they include monitoring conducted while employees are wearing respirators. For these reasons, Sterigenics has not provided average concentrations, as they have no real-world meaning. The Company also conducts badge monitoring on a short-term, task-specific basis. Sterigenics has not included this task-specific monitoring in the minimum and maximum concentrations reported in its response, as these data are not comparable to the eight-hour data, and the short-term data are even less useful for EPA's rulemaking purposes.

Request I-9 to I-15: *Describe all room area monitoring for ethylene oxide, including: room area monitored; description of monitoring performed; average, minimum, and maximum concentration; number of instrument points in the room; frequency of monitoring at each point; instruments used; detection limit for those instruments; and action levels and standard operating procedures for room area monitoring.*

Response: Sterigenics' facilities have no program that could properly be considered "room monitoring." The facilities are designed with several gas chromatography ("GC") monitoring ports that collect ethylene oxide concentrations periodically. Because the program exists for employee safety purposes and ethylene oxide concentrations in a room are not homogenous, the monitoring ports are not placed in locations that are intended to be representative of average ethylene oxide concentrations in a room. In addition, monitoring results are used solely to trigger alarms and further investigation. As a result, Sterigenics has left these spreadsheet cells blank.

Request I-16: *Describe any other types of ethylene oxide monitoring that have been conducted by the facility, such as near-source, ambient air sampling, or fenceline monitoring efforts.*

Response: Each Sterigenics facility monitors ethylene oxide emissions based on performance tests and monitoring plans approved for air pollution control devices under the NESHAP. The facilities also conduct personal monitoring, as detailed elsewhere in the response. The facilities do not have a program for external ambient air sampling, in part because a ubiquitous background concentration of ethylene oxide exists, making ambient air samples an unreliable way to characterize emissions. In 2019, the Company conducted an ambient monitoring effort of background concentrations in the Chicagoland area, and it has provided the results of that effort to EPA previously.

Request I-17: *Describe any dispersion modeling efforts conducted by the facility.*

Response: Each Sterigenics facility confirms its compliance with regulations related to ethylene oxide based on performance tests and parametric monitoring of air pollution control devices and process equipment under the NESHAP. None of Sterigenics' facilities has a program of performing air dispersion modeling on a routine basis. In some cases, permit applications require

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air dispersion modeling; when such modeling has been required as part of the most recent permit application, a description of that modeling is provided as part of the permit application being produced.

Request K-1 to K-13: *Provide number of unique cycles run at the facility, including total, for 510(k) products only, and for pre-market approval products only. If the facility plans to re-validate cycles to reduce ethylene oxide use, then provide: number of unique cycles revalidated so far; number left to revalidate; time needed to complete revalidation; cost of revalidation; current and target average ethylene oxide dose; anticipated change in number of nitrogen, air, and gas washes; anticipated change in dwell period time and aeration time; and anticipated annual cost savings from reduced ethylene oxide use.*

Response: As a contract sterilizer, Sterigenics runs a large number of FDA-required validation and re-validation cycles on behalf of its customers. Much of the requested information is the customer's data and information and may not be completely known by Sterigenics. In addition, Sterigenics is working with the FDA and several customers to reduce ethylene oxide concentrations and the total amount of ethylene oxide used in sterilization cycles but such information is not available at this time. As a result, Sterigenics has left the spreadsheet cells blank.

Request L-3: *Provide documentation of any studies done on quantifying ethylene oxide residuals in your products.*

Response: As a contract sterilizer, Sterigenics does not have any products. Sterigenics understands that its clients may generate some residuals information as part of FDA-required validation studies; however, any such information does not belong to Sterigenics and does not relate to any product that belongs to Sterigenics.

Request L-5: *Provide percent emission reduction, associated costs, and description of QA/QC for voluntary measures.*

Response: Sterigenics' facilities have numerous procedures and design features that have the effect of reducing emissions to a degree or in a manner that is not required by regulation and is, therefore, voluntary. Sterigenics is not reasonably able, without further definition and in the limited time provided for response, to identify and compile a list of those procedures and design features, estimate the emission reduction and cost associated with that list, and describe any QA/QC.

Request N-1: *Provide any process and instrumentation diagrams (P&ID) that are not included in previous attachments.*

Response: Sterigenics' facilities do not have a single set of P&IDs; rather, they have numerous P&IDs, of varying scopes and at varying degrees of detail, and created at different times. It is not possible in the time provided to review every P&ID to determine whether it is current and accurate, nor would such an exercise assist EPA. As described in the clarification to Request A-21, Sterigenics has produced general site layout diagrams.

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